IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

KYLE M. SWISHER.	)	
	)	
Plaintiff,	)	
vs.	)	NO. CIV-14-0028-HE
	)	
STRYKER CORPORATION,	)	
CORIN GROUP PLC, and	)	
CORIN USA LIMITED,	)	
	)	
Defendants.	)	

ORDER

Plaintiff Kyle M. Swisher filed this action in state court against defendants Stryker Corporation, Corin Group PLC and Corin USA Limited, Inc., asserting a negligence per se claim based on defendants' alleged violations of various federal regulations and specifications governing the design, manufacturing, marketing, sale and distribution of the Cormet Hip Resurfacing System. Plaintiff essentially claims that he was injured as the result of a defective Cormet System being surgically implanted into his right hip. Corin Group PLC and Corin USA Limited, Inc. (collectively "Corin") removed the action to federal court and they have filed a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6).[1]

When considering whether a plaintiff's claims should be dismissed under Fed.R.Civ.P. 12(b)(6), the court accepts all well-pleaded factual allegations as true and views them in the light most favorable to the plaintiff as the nonmoving party. S.E.C. v. Shields, ___ F.3d ___, ___ (10th Cir. 2014). All that is required is "a short and plain statement of the

[1]*Although it is titled a petition, because this action originated in state court, the court will refer to the pleading as a complaint.*

claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a)(2). The complaint must, though, contain "enough facts to state a claim to relief that is plausible on its face" and "raise a right to relief above the speculative level. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570, 555 (2007). "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Shields, ___ F.3d at ___ (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)). As explained by the Tenth Circuit, the new Twombly/Iqbal pleading standard "is a middle ground between heightened fact pleading, which is expressly rejected, and allowing complaints that are no more than labels and conclusions or a formulaic recitation of the elements of a cause of action, which the Court stated it will not do." *Id.* at ___ (quoting Khalik v. United Air Lines, 671 F.3d 1188, 1191 (10th Cir.2012)). "'Rule 8(a)(2) still lives'" and under it "'specific facts are not necessary; the statement need only give the defendant fair notice of what the ... claim is and the grounds upon which it rests.'" *Id.* (quoting Khalik, 671 F.3d at 1191-92). Context determines the "'nature and specificity of the allegations required to state a plausible claim.'" *Id. (*quoting Kan. Penn Gaming, LLC v. Collins, 656 F.3d 1210, 1215 (10th Cir.2011)). Considering plaintiff's negligence per se claim under this standard, the court concludes defendants' motion to dismiss should be granted.

In the complaint plaintiff alleges that Corin designs, manufactures, markets, sells and distributes implantable medical devices, including the Cormet Hip Resurfacing System, a

Class III medical device,[2] that the Cormet System was surgically implanted into his right hip in December 2009, and that he experienced significant pain after the surgery and multiple, varied health problems that seemed unconnected to the Cormet System. Physicians and other medical professionals allegedly told plaintiff that his symptoms were part of the recovery process from the surgery or were due to other causes. Plaintiff claims that, after his symptoms continued to worsen and he was experiencing short-term memory loss, he discovered through his own research that he could be suffering from "metallic blood poisoning caused by the shedding of metal ions from the Cornet System he had received." Doc. #1-2, p. 5. A blood test performed in September 2013 revealed, plaintiff alleges, that his "blood was contaminated with abnormally high levels of cobalt and chromium, both of which are metals contained in the cup and cap components of the Cormet system." *Id*. Plaintiff alleges that his health problems, which have required additional surgeries, were proximately caused by defendants' violations of various regulations promulgated by the Food and Drug Administration ("FDA"). Plaintiff lists in the complaint the regulations which he claims Corin violated.

Although plaintiff asserts in his response brief that he also has alleged that "the FDA has acknowledged the danger that metal-on-metal devices like the Cormet System might shed metallic ions and cause numerous complications" such as those he suffered, Doc. #9, p. 20,

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[2]*Congress, by passing the Medical Device Amendments of 1976 ("MDA"), "swept back some state obligations and imposed a regime of detailed federal oversight" for new medical devices.* Riegel v. Medtronic, Inc., *552 U.S. 312, 316 (2008). "The devices receiving the most federal oversight are those in Class III." Id. at 317. While the MDA includes a preemption clause, it does "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id. at 330.*

those allegation are not in the complaint. Also missing from the complaint are allegations showing "the defective nature of his Cormet System necessitates corrective surgery to remove the device entirely and replace it with an entirely new design." *Id.*[3]

The sole question raised by Corin's motion to dismiss is whether plaintiff has pleaded sufficient facts to state a negligence per se claim. Corin does not dispute that a parallel state law claim for negligence per se based on a violation of federal regulations is allowed under Oklahoma law. *See* Howard v. Zimmer, Inc., 718 F.3d 1209 (10th Cir. 2013).[4] What is missing, according to Corin, are facts demonstrating how specific FDA regulations were violated. Corin essentially contends that, in light of the rigorous Pre-Market Approval ("PMA") process and the Food and Drug Administration's continued strict oversight over Class III devices, little short of an FDA warning letter or enforcement action or recall, will suffice to state a parallel negligence per se claim against a Cormet manufacturer. While that may be going too far, the court does agree with Corin that something more is needed for plaintiff to get past a motion to dismiss.

The court realizes that individuals in the plaintiff's position are handicapped because, as several courts have noted,"[i]n the case of Class III medical devices, potentially valuable information related to PMA is kept confidential as a matter of federal law and formal discovery may be required before a plaintiff can fairly be expected to identify specific defects." Comella v. Smith & Nephew, Inc., 2013 WL 6504427, at *3 (N.D. Ill. Dec. 11,

[3]*The court is not expressing an opinion as to whether such allegations, if included in the complaint, would result in a different conclusion regarding its sufficiency.*

[4] *Plaintiff acknowledges in his response brief that he is not asserting a fraud claim, which would be preempted.*

2013). However, more is required to make out a parallel claim than conclusory statements that a defendant violated multiple regulations. Essentially all plaintiff alleges is that he was diagnosed with abnormally high levels of chromium and cobalt in his bloodstream, that the cup and cap components of the Cormet System are made of those two alloys, that "microscopic metallic particles . . . have rubbed off from the metal surfaces of the cap and cup components" and that the "shedding was the direct and proximate result of Defendants' violation of the PMA specifications and the applicable GMPs,[5] including but not limited to those identified above." Doc. #1-2, pp. 9-10.

Courts are not in agreement regarding how much must be pleaded by a plaintiff to state a claim challenging a Class III medical device. *Compare* Comella, 2013 WL 6504427, at *3-4[6] *with* Bass v. Styker Corp., 669 F.3d 501, 509-13 (5th Cir. 2012). However, the approach taken by the Fifth Circuit in Bass appears to be more in line with Twombly. In Bass the court contrasted allegations that it concluded were sufficient to plead a non-conclusory parallel claim based upon manufacturing defects resulting from violations of federal regulations with those that were not. The court concluded a plaintiff had pleaded enough to state a parallel claim when he alleged:

> (1) he received a Shell implant; (2) the FDA had previously warned Stryker of bioburden in excess of FDA regulations in its final rinse of the Shells; (3) after Bass's surgery, Stryker ultimately voluntarily recalled those Shells, including the Shell specifically used in Bass's implant; (4) Bass suffered from a loose

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[5] *"GMP" refers to "Good Manufacturing Practices".*

[6] *Although the specific allegations in the complaint are not included in the opinion, the court in Comella noted that "[a] post-operative report further revealed corrosion on the device at the modular junction and lab results consistent with metallosis." Comella, 2013 WL 6504427, at *1. Similar allegations are not found in plaintiff's complaint.*

> Shell due to a lack of bony ingrowth; and (5) the lack of bony ingrowth is a known effect of an excess of bioburden and manufacturing residuals on Shells.

Id. at 510. It found a complaint was "too conclusory to state a claim," *id.* at 509, which did

> not specify the manufacturing defect; nor d[id] it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor d[id] the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.

Id. (quoting Funk v. Stryker Corp., 631 F.3d 777, 782 (5th Cir. 2011).

Plaintiff's complaint has the same flaws as those rejected by the Fifth Circuit in Funk. The court concludes plaintiff has failed to satisfy the Twombly/Iqbal pleading standard. Accordingly, defendants' motion [Doc. # 7] is **GRANTED** and plaintiff's negligence per se claim is **DISMISSED**. As it is possible plaintiff may be able to correct the pleading deficiencies, he will be **GRANTED** leave to file an amended complaint by **April 4, 2014**. Otherwise this action will be dismissed.

Defendant Corin USA Limited noted in its motion that it was incorrectly sued as Corin USA Limited, Inc. The clerk is directed to correct the caption on the docket sheet to reflect the defendant's correct name.

IT IS SO ORDERED.

Dated this 14th day of March, 2013.

JOE HEATON
UNITED STATES DISTRICT JUDGE